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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,488	05/24/2001	Marcia A. Wise	7733.D2	3552

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FAY KAPLUN AND MARCIN, LLP  
150 BROADWAY, SUITE 702  
NEW YORK, NY 10038

EXAMINER
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GRAY, PHILLIP A

ART UNIT	PAPER NUMBER
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3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

09/864,488

Applicant(s)

WISE ET AL.

Examiner

Phillip Gray

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 56 and 59-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 56, 59-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to applicant's communication of 8/22/2006. Currently claims 56, 59-66 and 68-81 are pending. Claims 1-54 were previously cancelled and claims 55, 57, and 58 were previously withdrawn from considerations. Prosecution has been reopened to better explain previous rejections, make applicant aware of newly cited references, and make new rejections with newly discovered prior art. See rejections below.

#### *Response to Arguments*

Applicant's arguments with respect to claims 56, 59-66 and 68-8, have been considered but are moot in view of the new ground(s) of rejection. See rejections below.

#### *Drawings*

It is strongly suggested that applicant show a catheter including **first and second lumens extending therethrough from a proximal end of the catheter to a distal end** thereof as claimed. Figs. 1 and 3 **clearly do not show** what is claimed.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 56 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claim 56, it is unclear how applicant a catheter includes a first and second lumens extending there through from a proximal end of the catheter to a distal end of the catheter thereof when it appears from the drawings that the catheter has one distal end and two separate proximal ends.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 56, 59-66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Wijay et al. (U.S. Patent Number 5,158,540). Wijay discloses a low profile angioplasty perfusion catheter and method of use, which is insertable through a guiding catheter (see abstract, figures 1-4). Wijay discloses and teaches (and is fully capable of being) a system for establishing intermittent fluid communication within a patient's bloodstream, and comprises a catheter with first (such as annular passage 30) and second lumens (26) (see figures 2, 3, and paragraph at column 2 line 49-68), a first sealing balloon (16) positionable within the first lumen to prevent blood (or fluid) flow

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therein (or through) and a deflation mechanism for deflating the balloon (not numbered but described and to be connected to connection 3)(see detailed description at column 3 lines 49-61). Further Wijay discloses a method of sealing the catheter that comprises the acts of advancing the first deflated balloon (22) along the first lumen (30) and inflating the balloon to seal the lumen at the distal end thereof which would prevent fluid flow from entering or exiting (see description of use at column 4 lines 10-46) the distal end of the lumen. Wijay discloses that the balloon could be **selectively** inflated or deflated (see column 3 line 54-55) to seal passage 30 which is in fluid communication between blood vessel site and proximal end of catheter (nearer section 2 as in figure 1). Therefore it is examiners position since the proximal balloon can be selectively inflated and deflated (and since it blocks the flow through passage 30 while inflated) when the balloon is deflated ingress or egress of fluid flow through passage 30 would occur. And it is examiners position that this deflation (as previously noted) would take place while the catheter is in the blood vessel site. Further Wijay discloses a stem (near 14) within the lumen, and further the stem is fully capable of being selectively displaceable along the lumen through the central opening of the in the seal (as shown in figure 1 and describe in columns 2-4 generally). There are further ports adjacent the proximal end by which a flushing liquid under pressure is displaced within the lumen (i.e. 2,3,4,28, or 7). Further Wijay discloses steps of advancing a first balloon along a catheter and inflating the balloon to seal the catheter, deflating the ballon to open the seal and causing ingress or egress, further the balloon (and Wijay PTCA catheter) is withdrawn from the guiding catheter after the balloon is deflated (see column 2-4), and this method may be

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done multiple times for multiple treatments (since it is selectable) and it is examiners position that the lumen is purged with saline (column 4). Wijay discloses a device that contains a catheter (8, or 13) a balloon with stem (16) and a deflating mechanism and port (discussed above) and these elements are fully capable of satisfying all structural, operational, functional, and spatial limitations of the claims as currently written.

The following other prior art reads on the claims as currently written, and appropriate rejections are made below. Each are similar perfusion catheters and methods of use and perform similarly to the prior art disclosed above. See rejections below:

Claims 56, 59-66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski et al. (U.S. Patent 4,771,777). As discussed above and see figures 9 and see catheter 14 balloon 82 and stem 77 port 26 for example.

Claims 56, 59-66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Calderon (U.S. Patent 4,867,742). As discussed above and see figures 2, 3, and 5 and catheter 52, balloon 56, and ports 58, 54, 26, or 14.

Claims 56, 59-66, 68-69, and 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Cannon (U.S. Patent 5,403,274). As discussed above and see figures 1-3 and catheter 18 balloon 44 with stem near 32 and ports shown in figure 1 at proximal end of catheter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 59-64 are rejected under 35 U.S.C. 102(b) as anticipated by Wijay (as described above) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wijay in view of Burns et al U.S. Pat. No. 5,176,698. Wijay discloses the method substantially as claimed except for explicitly stating purging the first lumen. Burns discloses purging the first lumen (abstract and entire specification). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to purge the catheter of Wijay as taught by Burns to vent unwanted gases and liquids. As to claims

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60-62 (Burns col. 2) as to claim 63, (figure 6); as to claim 64, (the terminating act is performed by purging see above)

Claims 70-72, 74-79 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijay or alternatively Horzewski et al.(U.S. Patent 4,771,777), or alternatively Calderon (U.S. Patent 4,867,742) or alternatively Cannon (U.S. Patent 5,403,274) (see above). Wijay and alternatively Horzewski/Calderon/ or Cannon discloses the claimed invention and method except for being a side by side nonconcentric catheter tube/balloon. (applicant is merely attempting to claim two of the identical aforementioned tubes not having a common center) It would have been obvious to one having ordinary skill in the art at the time the invention was made to duplicate the device of Wijay or Horzewski/Calderon/ or Cannon, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8 (CA7 1977), and this would provide twice the output or input capabilities as well.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



PAG

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

